December 7, 2022

BK Medical Aps
% Sandra Theodoridis
SR Regulatory Affairs Specialist
Mileparken 34
Herlev, 2730
DENMARK

Re: K222441
Trade/Device Name: Ultrasound System 2300
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 28, 2022
Received: October 28, 2022

Dear Sandra Theodoridis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222441

Device Name
Ultrasound System 2300

Indications for Use *(Describe)*

Intended Use:
The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

Indications to Use:
The clinical applications and exam types include:
Fetal (including Obstetrics), Abdominal, Pediatric, Intra-operative, Intra-operative Neuro (also known as Neurosurgery), Laparoscopic, Small Organ (also known as Small Parts), Adult Cephalic (cephalic is also known as Adult Trans-cranial), Neonatal Cephalic, Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial), Cardiac Adult, Trans-esophageal (Cardiac) and Peripheral Vessel (also known as Peripheral Vascular).

Modes of Operation:
- 2D (B-Mode) including Tissue Harmonic Imaging
- M-Mode
- PWD Mode
- CFM Mode (C, VFI)
- Power Doppler
- Contrast Imaging
- CW Doppler
- Strain Elastography

Environment:
The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices)

Contraindications:
The Ultrasound System 2300 is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.
The Cardiac Adult application is not intended for direct use on the heart.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K222441

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. **Submitter:** BK Medical ApS
Mileparken 34
Herlev 2730
Denmark

Manufacturer: BK Medical ApS
Mileparken 34
Herlev 2730
Denmark

Primary Contact Person: Sandra Theodoridis
Senior Regulatory Affairs Specialist
BK Medical
Tel: (978) 578 9353
E-mail: stheodoridis@bkmedical.com

Date Prepared: August 11, 2022

II. **Device Names / Common Names / Classification Names:**

Trade Names:	**Ultrasound System 2300**
Common Name:	**Ultrasound System**
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

III. Identification of Predicate or Legally Marketed Devices:

- Primary predicate device: Ultrasound Scanner System bk2300 as cleared under 510(k) premarket notification No K180737.

Trade Name:	**Ultrasound System 2300**
Common Name:	**Ultrasound System**
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550, §892.1560, §892.1570
Classification Panel:	Radiology

- Reference predicate device: GE Logiq E10 cleared under 510(k) premarket notification No K211488.

Trade Name:	GE Logiq E10
Common Name:	GE Logiq E10
Classification Name:	Ultrasonic pulsed doppler imaging system
Product Code:	IYN (primary), IYO, ITX (secondary)
Class:	II
Regulation Number:	21 CFR §892.1550
Classification Panel:	Radiology

IV. Device Description

The Ultrasound System 2300 is a multi-purpose mobile, software-controlled diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms which are offered in different configurations/ models intended for urology, general imaging, surgical and anesthesiology applications.

The system consists of a mobile console (engine) that provides digital acquisition, processing and display capabilities. The user interface includes a conventional keyboard or a glass touchpad, a 19" Clinical Display Monitor (CDM). In addition, a variety of system accessories are available such as baskets, foot switch, printer start-up kit, remote control, and extra holders.

The Ultrasound System 2300 is available in the following marketing configurations:

1. bk3000 available with a conventional keyboard configuration. The bk3000 is primarily intended for applications such as urology and general imaging

2. bk5000 available with a conventional keyboard configuration. The bk5000 is primarily intended for surgery applications.

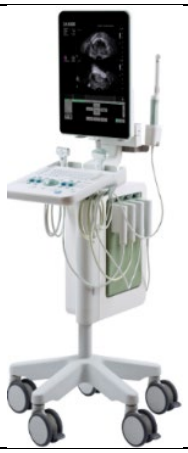
3. bkActiv is a configuration available with a glass user interface (UI). bkActiv is primarily intended for surgical and anesthesiology applications.

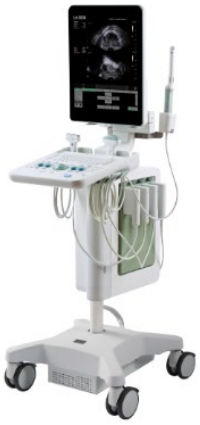
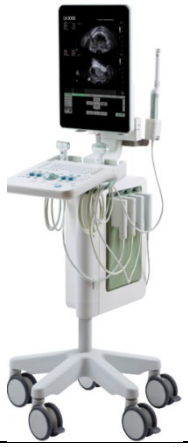
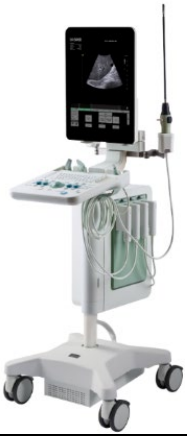
All configurations run on the previously cleared SW platform and HW platform (engine) (K180737). The various configurations of the Ultrasound System 2300 are intended to be used for different applications as described above with various transducers and options.

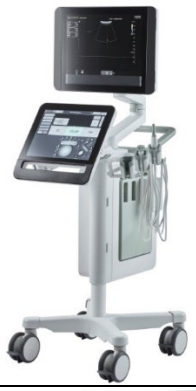
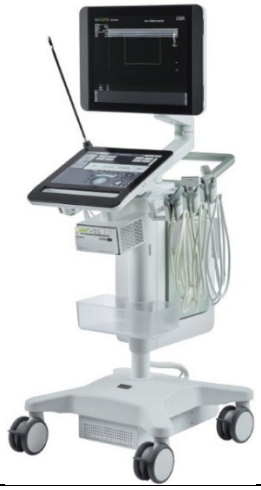
The primary difference between the system configurations (also refer to **Table 1**) are:

- bk5000 is the premier product offering with all features and probes available
- Bk3000 is a basic product offering with only a subset of features
- bkActiv is a configuration available with a glass user interface (UI). bkActiv is primarily intended for surgical and anesthesiology applications

Table 1: Ultrasound Scanner System bk2300 available configurations

Catalog/ Reference (REF)	**Model**		**Model Description**
2300	2300-01		BK3000 ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for Urology and General imaging applications.

Catalog/ Reference (REF)	Model		Model Description
2300	2300-11		BK3000 ULTRASOUND SYSTEM W/BATTERY This configuration is primarily intended for Urology and General imaging applications.
2300	2300-51		BK5000 ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for surgical applications.
2300	2300-61		BK5000 ULTRASOUND SYSTEM W/BATTERY This configuration is primarily intended for surgical applications.

Catalog/ Reference (REF)	Model		Model Description
2300	2300-56		BKACTIV ULTRASOUND SYSTEM W/O BATTERY This configuration is primarily intended for surgical and anesthesiology applications.
2300	2300-66		BKACTIV ULTRASOUND SYSTEM W/ BATTERY This configuration is primarily intended for surgical and anesthesiology applications.

The various configurations of the Ultrasound System 2300 are intended to be used with various multi-frequency transducers (see **Table 2**). The indicated uses are different and specific for each transducer listed.

- Linear Array
- Phased Linear Array
- Convex / Curved Array

The interaction with patients is dependent upon the transducer type which may include:

- Surface
- Inter-operative
- Laparoscopic
- Endocavity

Table 2: Transducers used with Ultrasound System 2300 configurations

Transducer	bk3000	bk5000	bkActiv
5C1e (9085) CURVED ARRAY TRANSDUCER	X	X	X
6C2 (9040) CURVED ARRAY TRANSDUCER	X	X	X
6C2s (9023) SMALL CURVED ARRAY TRANSDUCER	X	X	X
9C2 (9002) CURVED ARRAY TRANSDUCER	X	X	X
14L3 (9051) LINEAR ARRAY TRANSDUCER	X	X	X
13L4w (9011) WIDE LINEAR ARRAY TRANSDUCER	X	X	X
10L2w (9022) WIDE LINEAR ARRAY TRANSDUCER	X	X	
18L5 (9070) SMALL GIGH-FREQUENCY LINEAR ARRAY TRANSDUCER	X	X	X
18L5s (9081) SMALL GIGH-FREQUENCY LINEAR ARRAY TRANSDUCER	X	X	X
8L2 (9032) LINEAR ARRAY TRANSDUCER	X	X	X
E13C2 (9029) ENDFIRE ENDOCAVITY TRANSDUCER	X	X	
E14C4t (9018) TRIPLANE ENDOCAVITY TRANSDUCER	X	X	
X14CL4b (9048) BIPLANE ENDOCAVITY TRANSDUCER	X	X	
E10C4 (9019) ENDOCAVITY TRANSDUCER	X	X	
20R3 (9052) ANORECTAL TRANSDUCER	X	X	
N13C5 (9062) CURVED ARRAY TRANSDUCER	X	X	X
5P1 (9077) PHASED ARRAY TRANSDUCER	X	X	
X18L5S (9009) HOCKEY STICK TRANSDUCER	X	X	X
N11C5S (9063) BURR HOLE TRANSDUCER		X	X
I14C5I (9015) INTRAOPERATIVE I-SHAPE TRANSDUCER		X	X
I14C5T (9016) INTRAOPERATIVE T-SHAPE TRANSDUCER		X	X
I12C5B (9024) INTRAOPERATIVE BIPLANE TRANSDUCER		X	X
I12C5 (9034) MINI-TRANSDUCER		X	X
I12C4f (9066) LAPAROSCOPIC TRANSDUCER		X	X
X12C4 (9026) DROP-IN TRANSDUCER		X	X
X14L4 (9038) 3D ENDOCAVITY TRANSDUCER		X	
Rob12C4 (9096) ROBOTIC TRANSDUCER		X	X
N20P6 (9007) MINIMALLY INVASIVE TRANSDUCER		X	X
I13C3f (9076) ADVANCED LAPAROSCOPIC TRANSDUCER		X	X
I13C3fx (9078) **ADVANCED LAPAROSCOPIC TRANSDUCER WITH TRACKING**			**X**

V. Indications / Intended Use:

Intended Use:

The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis and puncture and biopsy guidance.

Indications for Use:

The clinical applications and exam types include:

- Fetal (including obstetrics)
- Abdominal
- Pediatric
- Intra-operative
- Intra-operative Neuro (also known as Neurosurgery)
- Laparoscopic
- Small Organ (also known as Small Parts)
- Adult Cephalic (Cephalic is also known as Adult Trans-cranial)
- Neonatal Cephalic
- Trans-rectal
- Trans-vaginal
- Musculo-skeletal (Conventional and Superficial)
- Cardiac Adult
- Trans-esophageal (Cardiac)
- Peripheral vessel (also known as Peripheral Vascular)

Modes of operation:

- B-Mode (including Tissue Harmonic Imaging)
- M-Mode
- PWD Mode
- CFM Mode (C, VFI)
- Power Doppler
- Contrast Imaging
- CW Doppler
- Strain Elastography

Environment:

The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices).

Contraindications

The Ultrasound System 2300 is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

The Cardiac Adult application is not intended for direct use on the heart.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 3: Substantial Equivalence Table of the proposed device with its predicate devices

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
Manufacturer	BK Medical ApS	BK Medical ApS	GE Healthcare	N/A
Common Name	Ultrasound system	Ultrasound system	Ultrasound system	Equivalent
Name (Configuration models)	bk3000 (2300-01, 2300-11) bk5000 (2300-51, 2300-61) bkActiv 2300-56, 2300-66	bk3000 (2300-01, 2300-11) bk5000 (2300-51, 2300-61)	LOGIQ E10	bkActiv 2300-56 & 66 are configurations of the cleared system K180737
Mode of Operation	B, M, PW, CFM, P, THI, CI, SE, CW Combination modes : 2D+M, 2D+PW, 2D+C+PW, 2D+P+PW, 2D+2D, 2D+2D (Biplane Imaging), 2D+(2D+C), 2D+(2D+P), 2D+THI, 2D+SE, 2D+CI	B, M, PW, CFM, P, THI, CI, SE, CW Combination modes: 2D+M, 2D+PW, 2D+C+PW, 2D+P+PW, 2D+2D, 2D+2D (Biplane Imaging), 2D+(2D+C), 2D+(2D+P), 2D+THI, 2D+SE, 2D+CI	B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography (Attenuation Imaging and Combined modes: B/M, B/Color, B/ PWD, B/Color/PWD, B/Power/PWD)	Identical – Primary predicate. Equivalent – reference predicate.
Intended Use	**Intended Use:** The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow analysis	**Intended Use:** The system is a diagnostic ultrasound imaging system used by qualified and trained healthcare professionals for ultrasound imaging, human body fluid flow	The LOGIQ E10 is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement,	Identical – Primary predicate. Equivalent – reference predicate.

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	Comment on Comparison
	and puncture and biopsy guidance. **Indications for Use:** The clinical applications and exam types include: • Fetal (including obstetrics) • Abdominal • Pediatric • Intra-operative • Intra-operative Neuro (also known as Neurosurgery) • Laparoscopic • Small Organ (also known as Small Parts) • Adult Cephalic (Cephalic is also known as Adult Trans-cranial) • Neonatal Cephalic • Trans-rectal • Trans-vaginal • Musculo-skeletal (Conventional and Superficial) • Cardiac Adult • Trans-esophageal (Cardiac) • Peripheral vessel (also known as Peripheral Vascular)	analysis and puncture and biopsy guidance. **Indications for Use:** The clinical applications and exam types include: • Fetal (including obstetrics) • Abdominal • Pediatric • Intra-operative • Intra-operative Neuro (also known as Neurosurgery) • Laparoscopic • Small Organ (also known as Small Parts) • Adult Cephalic (Cephalic is also known as Adult Trans-cranial) • Neonatal Cephalic • Trans-rectal • Trans-vaginal • Musculo-skeletal (Conventional and Superficial) • Cardiac Adult • Trans-esophageal (Cardiac) • Peripheral vessel (also known as Peripheral Vascular)	display and analysis of the human body and fluid.	

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
	Modes of operation: • 2D (B-Mode) including Tissue Harmonic Imaging • M-Mode • PWD Mode • CFM Mode (C, VFI) • Power Doppler • Contrast Imaging • CW Doppler • Strain Elastography **Environment:** The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g., hospitals, physician offices). **Contraindications** The Ultrasound System 2300 is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.	**Modes of operation:** • 2D (B-Mode) including Tissue Harmonic Imaging • M-Mode • PWD Mode • CFM Mode (C, VFI) • Power Doppler • Contrast Imaging • CW Doppler • Strain Elastography **Environment:** The Ultrasound System 2300 is intended for use in the professional healthcare environment (e.g. hospitals, physician offices). **Contraindications** The Ultrasound System 2300 is not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye. The Cardiac Adult application is not intended for direct use on the heart.		

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
Indications/Clinical Applications	- Abdominal - Intraoperative - Intraoperative – Neuro (Neurosurgery) - Pediatrics - Musculo-skeletal Superficial & Conventional - Neonatal Cephalic - Adult Cephalic (Transcranial) - Laparoscopic - Cardiac adult - Transesophageal (Cardiac) - Transrectal - Transvaginal - Fetal /Obstetrics - Small Organs (Parts) - Peripheral Vessel (Vascular)	- Abdominal - Intraoperative - Intraoperative – Neuro (Neurosurgery) - Pediatrics - Musculo-skeletal Superficial & Conventional - Neonatal Cephalic - Adult Cephalic (Transcranial) - Laparoscopic - Cardiac adult - Transesophageal (Cardiac) - Transrectal - Transvaginal - Fetal /Obstetrics - Small Organs (Parts) - Peripheral Vessel (Vascular)	- Fetal/Obstetrics - Abdominal (incl. Renal, Gynecology/ Pelvic) - Pediatric - Small Organ (Breast, Testes, Thyroid) - Neonatal Cephalic - Adult Cephalic - Cardiac (Adult and Pediatric) - Peripheral Vascular - Musculo-skeletal (Conventional and Superficial) - Urology (incl. Prostate) - Transrectal - Transvaginal - Transesophageal - Intraoperative (Abdominal and Vascular)	Identical – Primary predicate. Equivalent – reference predicate.
Application Environment	Professional healthcare facility environment	Professional healthcare facility environment	Professional healthcare facility environment	Identical
Users	Qualified and trained healthcare professionals	Qualified and trained healthcare professionals	Qualified and trained healthcare professionals	Identical
Patient Population	Adult, Pediatric	Adult, Pediatric	Adult, Pediatric + embryo and fetus	Identical – Primary predicate. Equivalent – reference predicate.
Transducer types	Surface Contact Intra-operative Laparoscopic Endocavity	Surface Contact Intra-operative Laparoscopic Endocavity	• Sector Phased Array • Convex Array • Micro convex Array • Linear Array • Matrix Array	Identical – Primary predicate. Equivalent – reference predicate – Reference does not have Laparoscopic but has Transesophageal

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
			• Volume probe (4D) • Split Crystal	
System Transducers	9002, 9007,9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9027, 9029, 9032, 9034, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9070, 9076, 9077, 9081, 9085, 9096, **9078**	9002, ,9009, 9011, 9015, 9016, 9018, 9019, 9022, 9023, 9024, 9026, 9027, 9029, 9032, 9038, 9040, 9048, 9051, 9052, 9062, 9063, 9066, 9070, 9076, 9077, 9081, 9085,	BE9CS-D, C1-6-D Convex, C1-6VN-D Convex, C2-6b-D, C2-7-D Convex, C2-7VN-D Convex, C2-9-D Convex, C2-9VN-D Convex, C3-10-D Convex, IC5-9-D Micro Convex Intracavitary, L2-9-D Linear, L2-9VN-D Linear, L3-9i-D, L3-12-D, L6-24-D Linear Array, L8-18i-D Linear, M5Sc-D XDclear Active Matrix Single Crystal Phased Array Transducer, ML4-20-D Matrix Array Linear, ML4-20VN-D Matrix Array Linear, ML6-15-D Matrix Array Linear, RIC5-9-D 4D Convex Volume Intracavitary, RAB6-D 4D Volume, 6S-D, 6Tc-RS + RS-DLP Transesophageal, P2D	The release of 9078 is new and part of this submission. The GE (VN) probes have a similar needle tracking sensor technology in them to the new 9078. 9007, 9034 and 9096 were released as per FDA's Guidance for Industry and FDA Staff - *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued June 27, 2019;* paragraph 5.1.3.3.

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
			Pencil Probe, P6D	
Biocompatibility	The Ultrasound system 2300 does not come in contact with the patient.	The Ultrasound system 2300 does not come in contact with the patient.	The Ultrasound system 2300 does not come in contact with the patient.	Identical
Hardware	<u>Clinical display monitor (CDM):</u> 19" Optical bonded glass front. Can be tilted and moved sideways. <u>Cart:</u> • Adjustable height and with 4 lockable wheels <u>Keyboard:</u> Traditional keyboard with multiple functionalities / specialized controls **or Glass touch UI** <u>Scan engine:</u> • 4 Transducer ports • 196 TX/RX channels • **Tracking Interface board**	<u>Clinical display monitor (CDM):</u> • 19" Optical bonded glass front. • Can be tilted and moved sideways. <u>Cart:</u> • Adjustable height and with 4 lockable wheels <u>Keyboard:</u> Traditional keyboard with multiple functionalities / specialized controls <u>Scan engine:</u> • 4 Transducer ports • 196 TX/RX channels	<u>Clinical display monitor (CDM):</u> • HDU 23.8" Wide screen High-Resolution LED backlight Display • OLED 22" Wide screen High-Resolution LED Display • 12-inch LCD touch screen • Color widescreen monitor (OLED and HDU monitors) <u>Keyboard:</u> Full-sized, backlit alphanumeric keyboard with multiple functionalities/specialized controls <u>Scan engine:</u> • 4 Active Probe Ports • 2 Inactive Probe Storage Ports	Additional Glass touch UI and new Tracking Interface board

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
			• VNAV Tracking Unit (installed as HW /option)	
Associated Needle tracking accessories	• **Tracking control unit** • **Portable EM field generator assembly (includes field generator and a mounting solution)** • **Clip-on needle sensor (CIVCO)** • **Needle sensor clamp kit (CIVCO)**	N/A	• Volume Navigation (VNAV)Option includes: - V Nav Probe Sensor - Volume Navigation Stand - Virtual Tracker Sensor	Equivalent needle tracking HW accessories between the proposed device and LOGIQ E10
Options	• 3D Freehand • 3D Professional • DICOM Encrypted • Contrast Enhanced Ultrasound • Vector Flow Imaging (VFI) • Varian Interface • Strain Elastography • Needle Enhancement (X-shine) • BrainLab Neuro Navigation • bkfusion (for Urology Procedures) • Wi-Fi • **bkViewer** (SW running on a MAC/Windows PC- not a medical device)	• 3D Freehand • 3D Professional • DICOM Encrypted • Contrast Enhanced Ultrasound • Vector Flow Imaging (VFI) • Varian Interface • Strain Elastography • Needle Enhancement (X-shine) • BrainLab Neuro Navigation • bkfusion (for Urology Procedures) • Wi-Fi	• **Volume Navigation**	Electromagnetic needle tracking is being offered on the proposed device as the 'LAP Ablation Navigation' option. The Logiq E10 includes this feature as 'Volume Navigation' option.

Characteristic	Ultrasound System 2300 **Proposed device (TBD)**	Ultrasound Scanner System bk2300 **Primary predicate (K180737)**	Ultrasound System LOGIQ E10 (Volume Navigation/GPS tracking option) **Reference predicate (K211488)**	**Comment on Comparison**
	- **LAP Ablation Navigation**			

VII. Performance Data

Summary of non-clinical /Performance - Bench Testing

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. The Ultrasound System 2300 and its applications comply with the following voluntary standards:

- ANSI/AAMI/ES 60601-: 2005/ (R) 2012 and A1:2012, C1:2009/ (R) 2012 and A2:2010/ (R) 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Ed. 4.0, 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-37 - Medical Electrical Equipment - Part 2-37: Ed. 2.1, 2017 Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
- IEC 62359: Ed. 2.1, 2017 - Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields
- IEC 60825-1: Ed. 2.0, 2007 - Safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]
- AAMI/ANSI/ISO 10993-1: 2018 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk management Process
- AAMI TIR-12:2010 and AAMI TIR-30:2011
- IEC 62304: 2006/A1:2016 - Medical Device Software Life-Cycle Processes (Software / Informatics)
- NEMA PS3.1 – 3.20 Digital Imaging and Communications in Medicine (DICOM)
- ISO14971: 2019 - Application of risk management to medical devices

The following quality assurance measures are applied to the development of the system:

• Risk Analysis

- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Animal Testing

Not applicable – animal testing was not required to support substantial equivalence to the predicate device.

Clinical Studies

Not applicable – clinical studies were not required to support substantial equivalence to the predicate device.

VIII. Conclusion

BK Medical ApS considers the proposed device to be as safe, as effective and performance is substantially equivalent to the predicate device(s).